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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,320	11/03/2005	Yoshiko Takayama	2005_1592A	1755

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
08/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/553,320	TAKAYAMA ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16 and 18-20* is/are pending in the application.

4a) Of the above claim(s) *14-16 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed June 28, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claim 13 has been amended.

   b. Claim 17 has been cancelled.

2. Claims 13-16, 18-20 are pending in the case.

3. Claim 13 is present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hellberg et al. (WO 03/020281) in view of McKerracher et al. (WO 99/23113) and Hara et al. (Protein kinase inhibition by fasudil hydrochloride promotes neurological recovery after spinal cord injury in rats).

Hellberg et al. teaches the use of compounds that promote neuron regeneration or neurite outgrowth for the treatment of conditions such as dry eye and other conditions

related to corneal nerve damage (e.g. corneal sensitivity after LASIK). The compounds are used promote neurite outgrowth or regenerate severed neurons, examples include bFGF(basic fibroblast growth factor), NGF (Nerve growth factor), neotrofin, idebenone, and clenbuternol (see full document, specifically Abstract, Page 4 line 16-Page 5 line 25, Page 6 line 12-23, Claim 1-4, 7-10, 13-16).

Hellberg et al. do not expressly teach the use of Rho kinase inhibitors such as fasudil hydrochloride.

McKerracher et al. teaches that Rho antagonists (Rho kinase inhibitors- e.g. C3) are effective agents for blocking myelin inhibition and stimulate axon growth and neurite outgrowth (neuritogenesis)(Abstract, Page line 10-20, Page 7 line 4-12). McKerracher also teaches that these Rho inhibitors are useful for treating conditions and ailments of the peripheral nervous system (PNS) and central nervous system (CNS) by increasing neurite extension, growth, or regeneration (Page15 line 6-15) . This includes spinal cord injuries and ophthalmic neurons as demonstrated by its application to retinal neurons and crushed optic nerves (Page 8 line 25-Page 9 line 2, Figure 5 and 7, Page 9 line 13-Page 10 line 18, Page 12 line 11-24, Page 29-34, Claim 22).

Hara et al. teaches that fasudil hydrochloride (HA1077, Rho kinase inhibitor) can promote neurological recovery after traumatic spinal cord injuries (SCI) as are other agents such as neurotrophic factors known in the art that improve neurological recovery in SCI (Introduction-Page 94, e.g. basic fibroblast growth factor-citation 5, Nerve growth factor-citation 16, 31, 44,) .

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize fasudil hydrochloride to promote neuron regeneration or neurite outgrowth for corneal injury, as suggested by McKerracher and Hara, and produce the instant invention. It would be obvious for one of skill in the art to use another neurite promoter such as fasudil for corneal injury as Hellberg et al. teaches the use of compounds that promote neuron regeneration or neurite outgrowth for corneal disorders, and Hara et al. teaches that fasudil (a known Rho kinase inhibitor) was an effective neuropromoter that recovered injured spinal neurons (spinal cord injury) and McKerracher teaches that the Rho inhibitors are neuron regenerators/promoters useful for PNS and CNS conditions like spinal cord injuries and retinal/optic neurons. Hara also addresses that neuropromotion was with fasudil and other neurotrophic factors which are the same ones in Hellberg, wherein they are functionally useful (equivalent). Wherein not only is it obvious to utilize a known neurite/neuron promoter (fasudil) for the same purpose as similar neurite/neuron promoters (neurotrophic factors) for a specific treatment (corneal nerve damage) when they have both been effective for a similar conditions and/or therapeutic result (neurological recovery of spinal cord injuries) with a reasonable expectation of success; it is also obvious to use a Rho inhibitor such as fasudil which is an effective and useful neuropromoter/regeneration (Hara), for a condition such as corneal injury where the treatment utilized compounds that can promote neuron regeneration or neurite outgrowth which encompasses Rho inhibitors like fasudil (Hellberg) and are taught to be useful for PNS and CNS conditions (McKerracher).

One of ordinary skill in the art would have been motivated to do this because it is desirable to use a known compound such as fasudil hydrochloride with known properties for promoting axon extension and regeneration, to treat the same conditions as another neurite/neuron promoters such as neurotrophic factors (e.g. bFGF, NGF) when it is they are both effective to treat neurological damage. It is desirable to have additional compounds that are effective neuropromoters for a treatment of corneal injury that utilizes neuropromoters as it is desirable for manufacturers to have different compounds useful for the same purpose and to have new methods of treatment for a known compound which allows for new sales.

Response to Arguments

7. Applicant's arguments with respect to claim 13 have been considered but are moot in view of the new ground of rejection.

Conclusion

8. Claim 13 is rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/
Examiner, Art Unit 1612
/Zohreh A Fay/
Primary Examiner, Art Unit 1612